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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,156	01/04/2002	Keisaku Okada	05090001BA	2583

7590 09/13/2004

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,156	OKADA ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed on 04 January 2002 has been received. Claims 1-7 are pending.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

3. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 09/120,192 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be timely made in this application. To satisfy the requirement of 37 CFR 1.55(a)(2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kouvonen et al (US Patent No. 5,965,458) in view of Williams et al (US Patent No. 6,080,400) and Krivan et al (US Patent No. 5,512,282).

Kouvonen discloses a test strip and method for rapid immunoassay of foodstuff for bacterial contaminants, for example. The test strip comprises a backing sheet and a receiving end pad and at a distance from a finishing end pad. A test membrane is provided between said pads. The membrane is intended for being brought into liquid flow contact with a sample. The test membrane preferably carries a test zone containing an immobile reagent and a control zone containing control substance. A label zone containing a mobile label is applied to the test membrane or into the absorbing pad at the receiving end, thus enabling the label to migrate to the test zone carried by liquid flow. The strip may also contain more than one test membrane in the same strip in order to test different analytes, or the same membrane may contain more than one zone each containing different reagents. The strip may also contain several different concentrations of the same reagent or label, in order to determine different analyte concentrations semiquantitatively. See abstract and column 3 through 4. Kouvonen teaches latex or metal colloid as labels, and that the test strip can be adapted for many tests including assays of food stuff. See column 5, lines 37-47 and column 8, lines 44-67. In one specific embodiment, Kouvonen teaches a method for the detection of occult blood in a fecal sample. Kouvonen teaches a test device designed for detection both human hemoglobin and human albumin. Hemoglobin is a more specific marker of blood which can occurs after intestinal bleeding in cancer patients, for example. See column 11, example 3.

Kouvonen differs from the instant invention in failing to teach the detection of verotoxin or verotoxin producing *Escherichia coli.*

Williams discloses that verotoxin producing *Escherichia coli* causes a life-threatening blood disorder that appears within 3 - 7 days following on set of diarrhea. Symptoms of hemolytic uremic syndrome (HUS) include renal glomerular damage, hemolytic anemia, thrombocytopenia, etc. Williams discloses that ingested organisms adhere to and colonize the intestinal mucosa, where toxins are released which cause endothelial cell damage and bloody diarrhea. Williams disclose a method for the detection of bacterial toxin by a sandwich assay utilizing antibodies directed against the bacterial toxin. Williams teaches that the immobilized antibody will be present in or on a solid support and exposed to a test sample and a reporter substance which detects the presence of bound toxin. See column 4, lines 50-62; column 5, lines 20-65; and column 31, lines 4-40.

Krivan discloses that antibiotics are contraindicated in the treatment of shiga-like toxins (i.e. verotoxin) producing *Escherichia coli* infection in humans and pigs. Antibiotics actually enhance toxin production by the bacteria. Therefore, their use increases the risk of developing complications such as HUS. Column 2, lines 39-56. Krivan et al also teach the assembly of various reagents into a diagnostic kit. See column 7, lines 10-16.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kouvonen to include detection of analytes such as verotoxin or verotoxin-producing *Escherichia coli* because Kouvonen teaches that their device provides the advantages of a simple test that can be performed anywhere and can be adapted for almost any type of analytes; and Williams and Krivan teach that the detection of verotoxin and verotoxin producing *Escherichia coli* is important because these toxins cause significant

intestinal bleeding in mammals including humans. A skilled artisan would have had a reasonable expectation of success and would have been motivate to use the device of Kouvonen to detect human hemoglobin and at least verotoxin or verotoxin producing *Escherichia coli* because Krivan teaches that it is important to identify specifically which bacteria causes the symptoms observed because in some instances, standard treatment such as antibiotics, are contraindicated. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to detect hemoglobin along with either verotoxin or verotoxin producing *Escherichia coli* in the same sample because this would provide the advantage of further confirming a diagnosis of possible early onset of HUS caused by verotoxin or verotoxin producing *Escherichia coli,* thus enabling better treatment actions for the disease.

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the device of Kouvonen as modified by Williams and Krivan into kits such as taught by Krivan for the advantages of convenience and economy.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
9/10/04